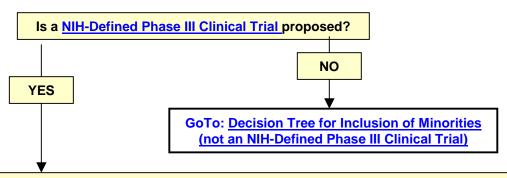
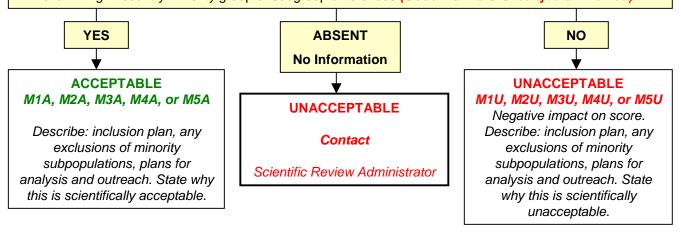


Decision Tree for Inclusion of Minorities In NIH-Defined Phase III Clinical Trials



Is minority representation acceptable?

- Strong evidence exists for significant racial or ethnic differences in intervention effect and study design or analysis can answer primary question(s) separately for each relevant subgroup and the analysis plan can detect significant differences in intervention effect? (Code M1: both U.S. minorities and non-minorities included) or
- 2. Strong evidence exists for NO significant racial or ethnic differences in intervention effect? (Code M1: both U.S. minorities and non-minorities, or Code M2: U.S. minorities only, or Code M3: U.S. non-minorities only) or
- 3. No clear evidence exists for or against significant racial or ethnic differences in intervention effect and study design and analysis plans will permit <u>valid analysis</u> of a differential intervention effect? (Code M1: both U.S. minorities and non-minorities) or
- 4. Some or all minority groups or subgroups are excluded because inclusion is inappropriate with respect to their health or because the research question is not relevant to them? (Code M1: both U.S. minorities and non-minorities, or Code M2: U.S. minorities only, or Code M3: U.S. non-minorities only) or
- 5. ONLY foreign (non-U.S.) subjects are involved **and** study design addresses any known scientific reasons for examining in-country minority group or subgroup differences (Code M5: no U.S. subjects involved)



Summary of Codes

Minority Representation Both minorities and non-minorities included Minorities only Non-minorities only Unknown (cannot be known) ONLY foreign (non-U.S.) subjects in study

Representation is scientifically...

Acceptable	Unacceptable
M1A	M1U
M2A	M2U
M3A	M3U
M4A	M4U
M5A	M5U